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HEALTH AND SENIOR SERVICES

SENIOR SERVICES AND HEALTH SYSTEMS BRANCH

DIVISION OF HEALTH FACILITIES EVALUATION AND LICENSING

Proposed New Rules: N.J.A.C. 8:43A-33

Proposed Amendment: N.J.A.C. 8:43A-2.2

Manual of Standards for Licensing of Ambulatory Care Facilities

Licensure Procedures

Application for Licensure

Programs of All-Inclusive Care for the Elderly (PACE) Organizations

Authorized By: Fred M. Jacobs, M.D., J.D., Commissioner, Department of Health and Senior Services (with the approval of the Health Care Administration Board).

Authority: N.J.S.A. 26:2H-1 et seq.

Calendar Reference: See Summary below for explanation of exception to the calendar requirement.

Proposal Number: PRN 2006-321.

Submit written comments by December 1, 2006 to:

John Calabria, Director
Certificate of Need and Acute Care Licensure Program
Division of Health Facilities Evaluation and Licensing
New Jersey Department of Health and Senior Services
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) is proposing licensure standards for Programs of All-Inclusive Care for the Elderly (PACE) organizations. PACE organizations provide services to individuals who are aged 55 or older, who have been certified by the Department to require nursing home care, who

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can live safely in the community at the time of enrollment, and live in a PACE service area.

PACE organizations provide all needed medical and supportive services to participants while maintaining the participant's independence in their homes as long as possible. These programs are pre-paid, capitated programs for beneficiaries who meet the eligibility requirements and elect to enroll.

PACE is a cooperative program between the United States Department of Health and Human Services (USDHHS) and the states. In New Jersey, the Department is responsible for overseeing the program.

The Department is proposing to incorporate the USDHHS regulations governing Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE) at 42 CFR Part 460 into a new subchapter, N.J.A.C. 8:43A-33.

The PACE regulations were originally adopted by the USDHHS on November 14, 1999 at 64 F.R. 66234.

42 CFR Part 460 provides the requirements for PACE under Medicare and Medicaid. A summary of 42 CFR Part 460 follows:

Subpart A, 42 CFR §460.2, contains the basis of the rules, which provide for Medicare and Medicaid payments to, and coverage of benefits, under PACE.

Subpart A, 42 CFR §460.4, addresses the scope and purpose of the rules.

Subpart A, 42 CFR §460.6, contains the definitions that apply to these rules.

Subpart B, 42 CFR §460.10 states that the purpose of this subpart is to set forth the application process.

Subpart B, 42 CFR §460.12 provides that the applicant must submit a complete application to Centers for Medicare & Medicaid Services (CMS) that describes how the applicant meets all the requirements of this part, as well as an assurance from the state-administering agency in the state in which the applicant is located, which in this case is the Department, that the state-administering agency considers the applicant to be qualified, as well as the state-administering agency's willingness to enter into a PACE agreement with the applicant.

Subpart B, 42 CFR §460.14 provides for priority consideration of PACE applications by CMS.

Subpart B, 42 CFR §460.16 provides for special consideration of PACE applications by CMS.

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Subpart B, 42 CFR §460.18 provides for CMS evaluation of applicants.

Subpart B, 42 CFR §460.20 provides for a CMS response within 90 days of the receipt of a completed application.

Subpart B, 42 CFR §460.22 requires an entity to state in its application the service area in which it intends to operate.

Subpart B, 42 CFR §460.24, limits the number of PACE program agreements.

Subpart B, 42 CFR §460.26 provides for the submission and evaluation of waiver requests.

Subpart B, 42 CFR §460.28 provides for a CMS response within 90 days of the receipt of a waiver request.

Subpart C, 42 CFR §460.30 addresses the required agreement between CMS, the state-administering agency, and the PACE program.

Subpart C, 42 CFR §460.32 provides the required content of a PACE agreement. This includes the designation of a service area, a description of the organizational structure and the administrative contacts, and a description of the services that are to be provided to participants.

Subpart C, 42 CFR §460.34 establishes that the duration of a PACE program agreement is one year.

Subpart D, 42 CFR §460.40 provides a list of violations for which CMS may impose sanctions.

Subpart D, 42 CFR §460.42 provides the sanctions for the violations specified in 42 CFR §460.40, which include the suspension of enrollment or payments by CMS.

Subpart D, 42 CFR §460.46 provides for civil money penalties in addition to the sanctions for violations addressed in 42 CFR §460.42.

Subpart D, 42 CFR §460.48 provides additional sanctions that may be imposed by CMS or the state-administering agency for violations addressed in 42 CFR §460.42, which include the termination of the PACE program agreement or the execution of a plan of correction.

Subpart D, 42 CFR §460.50 addresses the termination of a PACE program agreement.

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Subpart D, 42 CFR §460.52 provides for transitional care during the termination of a PACE program agreement.

Subpart D, 42 CFR §460.54 provides the termination procedures if CMS terminates a PACE program agreement.

Subpart E, 42 CFR §460.60 provides the organizational structure required for a PACE organization. A PACE organization is required to be, or a distinct part of, a governmental entity or a private, not for profit entity organized for charitable purposes.

Subpart E, 42 CFR §460.62 provides that a PACE organization is to operate under the control of an identifiable governing body or a designated person who functions as a governing body. The regulation also requires community representation on issues related to participant care and the establishment of a consumer advisory committee.

Subpart E, 42 CFR §460.64 establishes personnel qualifications for staff members of a PACE organization.

Subpart E, 42 CFR §460.66 provides for required staff training and the establishment of a staff training program.

Subpart E, 42 CFR §460.68 establishes program integrity standards.

Subpart E, 42 CFR §460.70 requires a PACE organization to have a written contract for services that the PACE organization is not providing directly and establishes requirements that these contracts must meet.

Subpart E, 42 CFR §460.71 provides that the PACE organization is responsible for oversight of direct participant care. The PACE organization must provide employees and all contracted staff with an orientation, develop a competency evaluation program for all direct care staff, and designate a staff member to oversee these responsibilities.

Subpart E, 42 CFR §460.72 provides that a PACE center must be designed, constructed, equipped and maintained in order to provide for the physical safety of participants, staff and visitors. The program is required to establish and implement procedures to address medical and non-medical emergencies, have emergency equipment available, as well as conduct an annual test of their emergency and disaster plan.

Subpart E, 42 CFR §460.74 requires PACE organizations to follow accepted policies and standard procedures in regard to infection control and to establish, implement and maintain an infection control plan.

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Subpart E, 42 CFR §460.76 provides for the safety, maintenance, and ability to communicate with the PACE center of transportation vehicles.

Subpart E, 42 CFR §460.78 establishes the requirements for dietary services.

Subpart E, 42 CFR §460.80 requires PACE organizations to have a fiscally sound operation, and provides ways the organization can demonstrate their fiscal soundness.

Subpart E, 42 CFR §460.82 addresses information that a PACE organization must include in its marketing materials. These include a description of the program, enrollment procedures, premiums, and a description of the plan and services offered. The rule further requires CMS approval of all marketing information.

Subpart F, 42 CFR §460.90 addresses PACE benefits under Medicare and Medicaid.

Subpart F, 42 CFR §460.92 lists the required services that a PACE benefit package is to include for all participants, regardless of the source of payment.

Subpart F, 42 CFR §460.94 lists the services that must be provided for Medicare participants, the hospital insurance benefits described in 42 CFR §409 and the supplemental medical insurance benefits described in 42 CFR §410.

Subpart F, 42 CFR §460.96 lists the services that are excluded from coverage under PACE.

Subpart F, 42 CFR §460.98 requires a PACE organization to establish and implement a written plan of service for each participant. The PACE organization must furnish comprehensive medical, health and social services that integrate acute and long-term care for each participant.

Subpart F, 42 CFR §460.100 requires PACE organizations to establish and maintain a written plan to provide emergency care for program participants.

Subpart F, 42 CFR §460.102 requires PACE organizations to establish an interdisciplinary team, and specifies the composition of this team.

Subpart F, 42 CFR §460.104 requires the interdisciplinary team to conduct an initial comprehensive assessment on each participant.

Subpart F, 42 CFR §460.106 requires the interdisciplinary team to promptly develop a plan of care that specifies the care needed to meet the participant's medical, physical, emotional, and social needs and to identify measurable outcomes that are to be achieved. The plan of care is to be evaluated on a semi-annual basis.

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Subpart G, 42 CFR §460.110 requires each PACE organization to have a written participant bill of rights, containing at a minimum, those specified at §460.112.

Subpart G, 42 CFR §460.112 addresses specific participant rights. Including respect and nondiscrimination, information disclosure, to choose provider's within the PACE organization's network, access to emergency services, to participate in treatment decisions, to have confidential healthcare information protected, and the right to a fair and efficient process for resolving differences with the organization.

Subpart G, 42 CFR §460.114 limits the use of restraints to the least restrictive and most effective method available.

Subpart G, 42 CFR §460.116 requires written policies to ensure that participants understand their rights, which are to be fully explained to them by the PACE organization.

Subpart G, 42 CFR §460.118 requires each PACE organization to establish and document procedures to respond to and rectify a violation of a participant's rights.

Subpart G, 42 CFR §460.120 requires each PACE organization to have a formal written process to evaluate and resolve a complaint expressing dissatisfaction with services received.

Subpart G, 42 CFR §460.122 requires each PACE organization to have a formal written appeals process, with specified timeframes for response, to address noncoverage or nonpayment of a service.

Subpart G, 42 CFR §460.124 requires PACE organizations to inform in writing, and to assist an applicant, in pursuing an appeal to Medicare or Medicaid.

Subpart H, 42 CFR §460.130 requires PACE organizations to develop, implement, maintain and evaluate a quality assessment and improvement program.

Subpart H, 42 CFR §460.132 provides that a PACE organization is to have a written quality assessment and improvement program and specifies the area that this program is to address.

Subpart H, 42 CFR §460.134 sets forth the minimum requirements for a quality assessment and performance improvement program.

Subpart H, 42 CFR §460.136 mandates the quality assessment and improvement requirements. A PACE organization must designate an individual to coordinate and oversee implementation of the program.

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Subpart H, 42 CFR §460.138 requires a PACE organization to establish one or more committees to evaluate data collected and address the implementation of the quality assessment and performance improvement program.

Subpart H, 42 CFR §460.140 requires a PACE organization to meet external quality assessment and reporting requirements as specified by the state-administering agency or CMS, in accordance with §460.202.

Subpart I, 42 CFR §460.150 sets the eligibility standards for enrollment in a PACE program.

Subpart I, 42 CFR §460.152 provides the enrollment process. The rule provides the minimum for the intake process and also addresses the denial of enrollment.

Subpart I, 42 CFR §460.154 addresses the required content of a participant's enrollment agreement.

Subpart I, 42 CFR §460.156 provides that, upon enrollment, the PACE organization is to give a participant a copy of the enrollment agreement, a membership card, emergency information and stickers for the participant's Medicare and Medicaid card that indicate that they are a PACE participant.

Subpart I, 42 CFR §460.158 provides that the effective date of enrollment is the first day of the calendar month following the receipt of the membership agreement by the PACE organization.

Subpart 1, 42 CFR §460.160 addresses the continuation of enrollment, which is until either the participant voluntarily disenrolls or is involuntarily disenrolled, pursuant to 42 CFR §460.164.

Subpart I, 42 CFR §460.162 provides that a participant may voluntarily disenroll at any time.

Subpart I, 42 CFR §460.164 provides the circumstances in which a participant can be involuntarily disenrolled.

Subpart I, 42 CFR §460.166 addresses the actions that must be taken when a PACE organization disenrolls a participant.

Subpart I, 42 CFR §460.168 requires a PACE organization to assist a participant's reinstatement in other Medicare and Medicaid programs after disenrollment.

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Subpart I, 42 CFR §460.170 addresses the manner in which a disenrolled participant may be reinstated in a PACE program.

Subpart I, 42 CFR §460.172 provides the documentation standards for a disenrollment.

Subpart J, 42 CFR §460.180 provides for Medicare payment to PACE organizations.

Subpart J, 42 CFR §460.182 provides for Medicaid payment to PACE organizations.

Subpart J, 42 CFR §460.184 provides the state-administering agency the authority for post-eligibility treatment of income for Medicaid participants.

Subpart J, 42 CFR §460.186 addresses the monthly premium that a PACE organization can charge a participant.

Subpart K, 42 CFR §460.190 provides for state-administering agency and CMS monitoring during a PACE organization's trial period.

Subpart K, 42 CFR §460.192 provides for state-administering agency and CMS monitoring after a PACE organization's trial period.

Subpart K, 42 CFR §460.194 requires a PACE organization to take action to correct deficiencies identified during a review.

Subpart K, 42 CFR §460.196 provides for the disclosure of review results.

Subpart L, 42 CFR §460.200 requires a PACE organization to collect data, maintain records, and submit reports as required by CMS and the state-administering agency.

Subpart L, 42 CFR §460.202 requires a PACE organization to establish and maintain a health information system.

Subpart L, 42 CFR §460.204 addresses financial recordkeeping and reporting requirements. PACE organizations are required to provide CMS and the state-administering agency with financial reports using an accrual basis of accounting that are verifiable by qualified auditors. PACE organizations must permit CMS or the state-administering agency to audit and inspect any books and records.

Subpart L, 42 CFR §460.206 requires the submission of a certified financial statement no later than 180 days after the end of the PACE organizations fiscal year.

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Subpart L, 42 CFR §460.210 addresses the maintenance of medical records.

A summary of the proposed new rules and the proposed amendment follows:

The Department is proposing to restructure N.J.A.C. 8:43A-2.2(b) to add a licensure application fee of \$1,750 and a renewal fee of \$750.00 for PACE organizations.

The Department is proposing to restructure N.J.A.C. 8:43A-2.2(m) and add a biennial inspection fee of \$200.00 for PACE organizations.

The Department is proposing a new subchapter at N.J.A.C. 8:43A-33 that would contain the rules governing the services that are to be offered by PACE organizations.

Proposed new N.J.A.C. 8:43A-33.1 addresses the scope of the subchapter, which is to provide for the licensure of PACE organizations by the Department of Health and Senior Services.

Proposed new N.J.A.C. 8:43A-33.2 provides that the purpose of these rules is to protect the health, safety and welfare of patients receiving services from a PACE organization in New Jersey.

Proposed new N.J.A.C. 8:43A-33.3 requires PACE organizations to comply with the rules of the USDHHS governing PACE organizations at 42 CFR Part 460 and the Department's rules for facilities providing primary care services at N.J.A.C. 8:43A-23.1(a) and 31.

Proposed new N.J.A.C. 8:43A-33.4 provides that PACE licensure applicants can apply for a waiver of the requirements at N.J.A.C. 8:43A and the manner in which the applicants are to apply for the waiver.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed amendment at N.J.A.C. 8:43A-2.2 and the proposed new rules at N.J.A.C. 8:43A-33 would establish the minimum rules for the licensure of PACE organizations. The intent of the rules is to ensure the quality of care provided to participants by PACE organizations. The PACE program would provide an alternative to participants who are eligible for nursing home services by providing them the services they need while allowing participants to remain in their own home.

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Entities that would be affected by the proposed amendment and new rules would include the organizations that would offer PACE services, participants who would receive services from a PACE organization, family members and caregivers of persons eligible for or who would participate in PACE, and staff who would work for a PACE organization.

The proposed amendment and new rules would ensure that PACE organizations provide quality services to participants and would provide PACE organizations with a clear delineation of the requirements for licensure and operation in New Jersey.

Economic Impact

PACE provides a means by which health care costs may be contained. The variety of services offered to the participant in their homes should serve to avoid the higher costs associated with inpatient care. Adoption of the proposed amendment and new rules would enable the Department to license PACE organizations to provide services to participants.

The proposed amendment and new rules would not impose any additional costs on the State budget, on participants in the PACE program, or on the Department. The proposed amendment and new rules may result in a costs savings to the State, as participants in the PACE program are individuals who may otherwise require placement in nursing homes, which have a higher Medicaid reimbursement rate.

Entities seeking to obtain licensure as PACE organizations would incur initial and renewal licensure and biennial inspection fees as provided in the proposed amendment at N.J.A.C. 8:43A-2.2, and as follows. The initial PACE organization licensure application fee would be \$ 1,750, and the annual renewal fee would be \$ 750.00. The biennial inspection fee would be \$ 200.00. The fees proposed for PACE organizations are identical to those currently be charged for ambulatory care centers providing primary care services.

Staffing and the services that PACE organizations are to provide to participants are identical to the Federal standards. The Department is not imposing any additional costs on providers.

The proposed amendment and new rules are not expected to have an economic impact on nursing homes, as the number of PACE program participants is not expected to be large, and PACE programs are to provide inpatient services when appropriate.

Federal Standards Statement

The proposed amendment and new rules would not impose standards on PACE organizations that exceed those contained in the applicable Federal standards, therefore, a Federal standards analysis is not required. The applicable Federal

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standards for PACE organizations may be found at 42 CFR Part 460.

Jobs Impact

The Department does not anticipate that the proposed amendment and new rules would result in an increase or decrease in the number of jobs available in the State.

Agriculture Industry Impact

The proposed amendment and new rules would not have an impact on the agriculture industry.

Regulatory Flexibility Analysis

The proposed amendment and new rules would establish initial standards for the licensure of PACE organizations. The proposed amendment and new rules would establish the minimum standards necessary to ensure that participants receiving PACE services receive suitable care. As these are the initial licensure rules, the Department is unable to estimate how many entities would be eligible for, or would ultimately receive, licensure as PACE organizations. Likewise, the Department is unable to estimate whether these entities would be considered small businesses under the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq.; however, the Department expects that most entities that would be eligible for, or that would ultimately receive, licensure as PACE organizations would be small businesses.

To address the impact the proposed rules would have on PACE organizations, the Department has placed the waiver requirement in the PACE licensing rules at proposed N.J.A.C. 8:43A-33.4 to make it readily apparent to PACE organizations that the opportunity to request a waiver for standards that may not apply is available to them.

The rules would impose reporting, recordkeeping and compliance requirements on the providers of PACE services. The reporting, recordkeeping, and compliance requirements are the same as those imposed on PACE organizations and ambulatory care providers under existing Federal regulations, described in the Summary above. The Department is not proposing any additional reporting, recordkeeping, or compliance standards that are not already imposed on PACE organizations under the Federal PACE program regulations, described in the Summary above.

The rules have been designed to minimize the adverse impact on small businesses, while ensuring the provision of quality care to participants. The Department has determined that compliance with the rules are necessary for all organizations that seek licensure to provide PACE services, in the interest of public health and safety, and

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that there should be no differentiation in requirements based on business size.

The costs of compliance are as discussed in the Economic Impact above.

Smart Growth Impact

The Department does not anticipate that the proposed new rules and amendment would have an impact on the achievement of smart growth or implementation of the State Development and Redevelopment Plan.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

8:43A-2.2 Application for licensure

(a) (No change.)

(b) The Department shall charge separate nonrefundable fees for the filing of an application for licensure and each licensure renewal of an ambulatory care facility in accordance with the following schedule:

Service	Application	Renewal
1.-17. (No change.)		
18. PACE organization	\$1,750	\$750

(c)-(l) (No change.)

(m) Each ambulatory care facility shall be assessed a biennial inspection fee in accordance with the schedule set forth **in the table** below.

1. This fee shall be assessed in the year the facility will be inspected, along with the annual licensure fee for that year.

2. The fee shall be added to the initial licensure fee for new facilities.

3. Failure to pay the inspection fee shall result in nonrenewal of the license for existing facilities and the refusal to issue an initial license for new facilities.

4. This fee shall be imposed only every other year even if inspections occur more frequently and only for the inspection required to either issue an initial license or to renew an existing license.

5. This fee shall not be imposed for any other type of inspection.

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Service

Inspection Fee

1.-17. (No change.)

18. PACE Organization..... \$200

[18.] 19. (No change in text.)

SUBCHAPTER 33. PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) ORGANIZATIONS

8:43A-33.1 Scope

All PACE organizations as defined at 42 CFR §460.6 incorporated herein by reference, as amended and supplemented, shall be licensed by the Department of Health and Senior Services.

8:43A-33.2 Purpose

The purpose of this subchapter is to protect the health, safety and welfare of participants in a PACE organization in New Jersey and to establish PACE licensure standards by appropriately blending Federal and State physical plant and operational requirements.

8:43A-33.3 Compliance requirements

(a) All PACE organizations shall comply with the regulations of the United States Department of Health and Human Services at 42 CFR Part 460, incorporated herein by reference, as amended and supplemented.

(b) All PACE organizations shall comply with requirements for facilities providing primary care services at N.J.A.C. 8:43A-23.1(a) and 31.

8:43A-33.4 Waiver requests

(a) An applicant for licensure as a PACE organization may request a waiver of specific standards in N.J.A.C. 8:43A that may not apply to the service the applicant proposes.

(b) Waiver requests shall follow the process outlined at N.J.A.C. 8:43A-2.9.

(c) Waiver application forms are available at the Department's Forms page at <http://web.doh.state.nj.us/forms> or from:

Director

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**Certificate of Need and Acute Care Licensure Program
Division of Health Facilities Evaluation and Licensing
New Jersey Department of Health and Senior Services
PO Box 360
Trenton, NJ08625-0360**